



UNITED STATES PATENT AND TRADEMARK OFFICE

cl
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/765,943

01/29/2004

Yasuyuki Numajiri

00862.023438.

1830

5514

7590

06/21/2006

FITZPATRICK CELLA HARPER & SCINTO
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

EXAMINER

SHAW, AMANDA MARIE

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 06/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/765,943

Applicant(s)

NUMAJIRI, YASUYUKI

Examiner

Amanda M. Shaw

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 1-5, 10-14 and 20-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-9, 15-19, and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/17/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election of Group II with traverse in the reply filed on May 30, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 6-9, 15-19, and 25 have been examined herein.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-9, 15-19, and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6-9, 16-19, and 25 are indefinite over the recitation of the phrase "to test a specimen". This phrase is considered indefinite because it is unclear if the specimen being tested is a specimen obtained from the subject (i.e. blood, tissue, urine, etc.) or if the specimen being tested is from something other than the subject. Therefore the scope of the claims cannot be determined.

Claims 6-9, 16-19, and 25 are indefinite over the recitations of "analyzing a pattern corresponding to the first DNA probe" and "analyzing a pattern corresponding to the second DNA probe". Corresponding is not an art recognized term to describe the

Art Unit: 1634

relationship between a pattern and a probe. Because the term "corresponding" has not been clearly defined in the specification and because there is no art recognized definition for this term as it relates to patterns and probes, one of skill in the art cannot determine the meets and bounds of the claimed subject matter.

Claims 15-19 and 25 are indefinite over the recitation of the phrase "the pieces of identification information" in Claim 15. There is insufficient antecedent basis for this limitation in the claim.

Claim 17 is indefinite over the recitation of the phrase "recording the test information generated in the generation step on the medical information card". This phrase is considered indefinite because it is unclear if the test results are being recorded on the card or if they are just being recorded somewhere else. Therefore the scope of the claims cannot be determined.

Claims 17 and 19 are indefinite over the recitation of the phrase "the basis of the first DNA probe" in Claim 15. There is insufficient antecedent basis for this limitation in the claim.

Claim 19 is indefinite over the recitation of the phrase "recording the identification information acquired in the first acquisition step on the medical information card". This phrase is considered indefinite because it is unclear if the identification information is being recorded on the card or if they are just being recorded somewhere else. Therefore the scope of the claims cannot be determined.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6, 7, 15, 16, 18, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beecham (US Patent 5876926) in view of Staub (US Patent 6187540) and further in view of Wohlgemuth (US Patent 6905827).

Regarding Claim 6 Beecham teach a method comprising collecting a sample from a test subject and taking biometric data (i.e. gene sequences) from the test subject. First the biometric data is read to determine the identity of the subject and then the sample can be screened for infectious disease monitoring (e.g. HIV) or for genetic testing (e.g. BRCA1 gene). The biometric data permit a high order of probability of correlation of the test subject with the sample and with test results derived from the sample (Abstract, Columns 4, 5, and 10).

Beecham et al do not teach a method which utilizes a DNA microarray to determine the identity of a subject and to test a sample for a disease or genetic condition.

However Staub teach that DNA microarrays can be used to determine the identity of newborn babies. Specifically Staub et al teach that the arrays can comprise

Art Unit: 1634

thousands of oligonucleotide probes. Sample nucleic acid is allowed to hybridize with the probes and the hybridization conditions can be varied so that sample nucleic acid will only hybridize to a given probe if a perfect match is found. The hybridization pattern is then read and the identity of the subject can be determined (Column 7).

Additionally Wohlgemuth et al teach that cDNA microarrays can be used to detect the expression level on one or more genes and thereby enable one to diagnose or monitor disease (Abstract). Wohlgemuth also teach that DNA microarrays can have several subsets of probes which can be used for different purposes. Specifically Wohlgemuth et al teach that a diagnostic nucleotide set identified as a subset of sequences on a cDNA microarray can be utilized for diagnostic (or prognostic, or monitoring, etc.) purposes on the same array from which they were identified (column 48).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Beecham et al so as to have analyzed the biometric data using a DNA microarray comprising a set of probes which can be used to determine the identity of a subject and a set of probes which can be used to test the sample for a disease or genetic condition in order to have achieved the benefits of using a method which allows for a powerful means of analyzing genetic information which utilizes automated scoring techniques and sophisticated data analysis software for collecting large amounts of data very quickly. Additionally having both probe sets on one microarray permits a high order of probability of correlation of the test subject with the sample and the test results derived from the sample.

Regarding Claim 7 Beecham et al teach a method further comprising a storage unit configured to store the identity of the subject and a past test result. Specifically Beecham et al teach a method wherein the biometric indicia (i.e. gene sequences) and the test results are stored as a single record in a data base (Column 7).

Regarding Claim 15 Beecham et al teach a method further comprising obtaining identification information of the subject recorded on a medical card held by the subject and comparing the information on the card to the information obtained from the analysis of the first set of probes to determine if the identities match. Specifically Beecham et al teach a method for retrieving medical data from a database. The method includes steps of providing a biometric reading by a user (such as a card), receiving medical data from a database when the biometric reading positively correlates with a biometric reading associated with the medical data stored in the database and displaying the medical data only in response to the user's biometric reading whose medical records are being accessed (Column 8).

Regarding Claim 16 Beecham et al do not teach that a DNA microarray is used to test a specimen.

However, Wohlgemuth also teach that DNA microarrays can have several subsets of probes which can be used for different purposes. Specifically Wohlgemuth et al teach that a diagnostic nucleotide set identified as a subset of sequences on a cDNA microarray can be utilized for diagnostic (or prognostic, or monitoring, etc.)

purposes on the same array from which they were identified (column 48). The diagnosis is based on the hybridization pattern formed.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Beecham et al so as to have used a DNA microarray comprising a set of probes which can be used to test the sample for a disease or genetic condition in order to have achieved the benefits of using a method which allows for screening of one or several genes at once to determine if a disease or genetic conditions is present.

Regarding Claim 18 Beecham teach a method wherein a warning is given when it is determined as a result of comparison in the comparison step that the subject identified on the basis of the first DNA probe group does not coincide with that recorded on the medical information card. Specifically Beecham teach that when the biometric data submitted by the user does not match stored biometric data the data retrieval process is either terminated or the user is asked to enter new or revised biometric data (Column 18). This is being interpreted as a warning.

Regarding Claim 25 Beecham teach a method wherein the reading of the hybridization pattern of the second DNA probe group is inhibited if it is determined as a result of comparison in the comparison step that the subject identified on the basis of the first DNA probe group does not coincide with that recorded on the medical information card. Specifically Beecham teach that when the biometric data submitted by the user does not match stored biometric data no stored medical information can be

Art Unit: 1634

released until the biometric data being entered by the user matches the biometric data stored in the database (column 18).

4. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beecham (US Patent 5876926), Staub (US Patent 6187540), and Wohlgemuth (US Patent 6905827) in view of Noblett (US Patent 6362004).

The teachings of Beecham, Staub, and Wohlgemuth are presented above.

The combined references do not teach that the DNA microarray has a first indicator which indicates the first DNA probe group and a second indicator which indicates the second DNA probe group.

However Noblett et al teach the use of fiducial marks on microarrays to precisely determine the location of each probe on the array. Noblett et al teach that microarrays may contain multiple fiducials which can be used for positioning. Additionally Noblett teaches that fiducials can be used to differentiate between arrays when there are multiple arrays on a microarray (Column 7).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Beecham et al so as to have used a DNA microarray comprising a set of fiducials in order to have achieved the benefits of Noblett of using a method utilizes fiducial marks in order to determine the location of each probe on the array.

5. Claims 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beecham (US Patent 5876926), Staub (US Patent 6187540), and Wohlgemuth (US Patent 6905827) in view of Honda (US Patent 6021393).

The teachings of Beecham, Staub, and Wohlgemuth are presented above.

The combined references do not teach a method comprising a recording step wherein the identification information and test results information are recorded on the patient's medical information card.

However Honda et al teaches the concept of portable memory cards carried by a patient to store the patient's personal medical information. The card can store the results from medical tests and various personal information. Then when the patient goes to the hospital or to see a doctor for the first time the patient can let the doctor know about his or her morbid state by only presenting the medial information card. (Abstract and Column 3).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Beecham et al so as to have included a recording step wherein the identity information and the test results are recorded on a medical identification card that the patient can keep in order to have achieved the benefits of Honda of providing a medical information card that can store the patients medical data allowing his medical history to be readily available to treating physicians thereby cutting down on hospital mistakes made by doctors.


Conclusion

6. No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda M. Shaw whose telephone number is (571) 272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda M. Shaw
Examiner
Art Unit 1634
June 19, 2006


CARLA J. MYERS
PRIMARY EXAMINER